

REMARKS

Claims 1-10, 12-14, 18-20, 22, 23, 25-29, 33, 60-63, 72, 73, 80, 114-116 and 127 are active. Claims 11, 15-17, 21, 24, 30-32, 34-59, 64-71, 74-79, 81-85, 88-113, 117-126 and 128-138 are subject to restriction and are withdrawn from consideration. The restriction is final. Claims 86 and 87 are canceled. Claims 114-116 are rejected under 35 USC 101. Claims 1-3, 7-9, 13, 14, 18, 20, 23, 25, 28, 29, 33, 60-63, and 80 are rejected under 35 USC 102e as being anticipated by Anderson et al. Claims 4-6, 10-12, 19, 22, 26, 27, 72, 73, 114-116 and 127 are rejected under 35 USC 103 as being unpatentable over Anderson 6,200,347.

Minor amendment is made to claims 67-69 in the interest of clarity and consistency.

The rejection of claim 114 under 35 USC 101

Claim 114 is amended as suggested to change "thereon" to --direction--. See applicants' prior response for further arguments regarding this claim and incorporated in their entirety herein. It is believed that this claim is statutory, that this basis of the rejection is overcome and the rejection should be withdrawn.

The Substantive Rejection (over Anderson)

Claims 1, 60, 62

Amended claim 1 calls for:

A spinal fusion implant for fusing together two adjacent vertebra comprising:

a first member having first and second opposing sides and a first bore defining a central longitudinal first axis, the first bore being in communication with at least the first side; a second member having third and fourth opposing sides and a second bore in communication with at least the third side, the second bore defining a second central longitudinal axis, the first and second axes forming a first pair; and an elongated first pin located in the first and second bores for securing the first member to the second member at the interface formed by the facing first and third respective sides, the pin having first and second sections and at least one first outermost peripheral surface defining a first transverse dimension therebetween at the first section defining a third central longitudinal axis, the pin having at least one second outermost peripheral surface defining a second transverse dimension therebetween at the second section defining a fourth central longitudinal axis, the third and fourth axes forming a second pair; one axis of at least one of the first and second pair of axes being offset relative to the other axis of the at least one pair of axes so as to place the pin in relative compression and tension in the first and second bores for providing a compressive load on the surface of the first and second bores to frictionally secure the members together (underlining added)

The applicants' undersigned attorney and the Examiner had a telephone interview on April 22, 2004 in which the undersigned requested that the Examiner explain the Office Action basis for the continued rejection of claim 1 over Anderson as this was not understood. During that interview, the Examiner explained that the basis for his conclusion is Fig. 16 of Anderson which shows a pin with bifurcated leg portions. He stated that this pin anticipated original claim 1. He stated that each of the leg portions has a longitudinal axis that is offset from the axis of the solid portion of the pin from which the legs depend. Each leg forms a section as claimed. He

stated that when the pin is larger in diameter than the bore, col. 28, line 55, that the leg portions will bend and when bent will cause both tension and compression in the legs. He stated that this figure thus meets claim 1.

A further portion of that interview is also reflected in an Office paper dated April 23, 2004. This paper summarizes a telephone proposal by applicants to amend the claims regarding the pin and implant bores offset relationship to overcome Anderson. In particular, it was proposed that the third and fourth central longitudinal axes are respectively defined by a first and second transverse dimensions between the outermost surfaces of the pin. The Examiner agreed that this structure would distinguish over Anderson. This structure is showed by the underlined portions of amended claim 1. Similar changes were proposed for claims 60 and 62 and are included in amended claims 60 and 62 herein.

The above amended claim 1, and amended claims 60 and 62 include the proposed subject matter of that interview. These claims are believed to distinguish over Anderson since each of the legs of Anderson's Fig. 16 embodiment defines a longitudinal axis using an interior surface and not an outermost peripheral surface of the pin. The legs together may define a longitudinal axis based on their combined outer peripheral surfaces, but this latter axis is not offset from the axis of the solid head portion of the pin from which the legs depend. For these reasons, claim 1 is believed allowable.

Claims 60 and 62 include structure that also distinguishes over Anderson similarly as claim 1. These claims are believed allowable.

The Substantive Rejections under 103(a)

Claim 72

Claim 72 is rejected under 35 USC 103 over Anderson.

Claim 72 calls for:

An implant comprising:
a first planar member having two opposing broad surfaces having a periphery defining a first plurality of edges;
a second L-shaped member having a first base member defined by a second plurality of edges and a first leg extending from the base member at one base member edge forming a first recess, the first member being disposed in the first recess with an edge of the first member abutting the first leg, the edges of the first base member and the edges of the first member being coextensive; and
means for securing the first member to the second member lining added)

The Office Action states that in connection with claim 10, which the Action equates with claim 72, that an L-shaped abutment would be obvious in order to simplify the process of forming the Anderson disclosed interlocking means, col. 14, lines 2-20, especially when supplemented with locking pins. This is not true. The claimed L-shape structure is not an interlocking means as disclosed by

Anderson and is not suggested by this reference. This reference does not go so far. This section of Anderson refers to figures 39-41 and refers to the term interlocking as comprising **any pattern** (col. 14, line 3) on a bone portion to engage or interlace with another bone portion. Figs. 39-41 show examples of such patterns. Applicants' claimed structure does not involve such a bone pattern formed on a surface or surfaces which interlace as disclosed by Anderson. The Anderson patterns are saw tooth or other interlaced configurations on a surface of the bone portions. Examples given are step patterns, saw tooth patterns, ridge patterns, patterns that define mortise and tenon joints and lock and key type patterns. One bone portion has a protrusion and a depression as a discrete pattern or may be continuous as in grooves, referring to figures 39-41. Discrete patterns may include protrusions and corresponding depressions, lines 15-20, and continuous patterns include grooves and so on. These are patterns on a surface. That is not what is being claimed. No surface patterns are involved in the claim 72 structure which is different in kind from that disclosed by Anderson. The abutting surfaces in applicants corresponding figures are shown smooth and not including protrusions or depressions which interlace and interlock as disclosed by Anderson.

Throughout this referred to patent section, the patent refers to interlocking patterns, col. 14, lines 1, 2, 17, 30, 34. This interlocking pattern relationship as

described by Anderson is foreign to what is claimed. The claim does not call for a pattern of any type or configuration on any surface of the mating members as described by this reference. The claimed surfaces have no relationship to the disclosed Anderson patterns. The reference is not so all encompassing as the Office Action construes it to be.

Claim 72 calls for a first planar member and a second L-shaped member with the first member disposed in the recess form by the L-shaped second member. This recess is not a pattern on a surface as contemplated by Anderson. It is a macro recess formed by a peripheral wall and not by depressions and protrusions as disclosed by Anderson. See applicants' figures 34, 37, 42, 62 and 72 for example, wherein there are no interlocking patterns on the adjacent bone surfaces as disclosed by Anderson. None of the Anderson figures discloses or makes obvious what is claimed, as Anderson does not show or suggest the claimed configuration. Applicants disagree that this reference discloses or suggests what is claimed. The Office is required by the MPEP and the rules to provide a reference to show what is claimed. This the Office has not done because the so called patterns of Anderson are not used or claimed in claim 72. This claim is directed to different subject matter than that disclosed by the reference.

Anderson does not disclose or suggest the claimed L-shaped second

member and the first member, without any interlocking patterns on their interface surfaces, nor is any motivation provided for modifying Anderson to arrive at the claimed L-shaped member combined with the first member as claimed based on col. 14, lines 1-39 of the reference. The claim is not directed to bare interlocking arrangement as appears to be suggested by the Action. This conclusion begs the issue, misconstrues the claim, and uses generalities not suggested or disclosed by the reference to reconstruct the specific claimed invention. No convincing line of reasoning is provided to support the conclusion. This claim is believed allowable and this basis of the rejection is believed in error and should be withdrawn.

Claim 80

This claim calls for:

A spinal implant comprising:
a stacked plurality of planar cortical bone sheets, the implant having a length dimension in a given direction, the sheets each having an interface surface abutting an adjacent sheet extending transversely the length direction and a bore at the interface surface; and a cortical bone pin extending in the length direction in said bores for securing the sheets together (underlining added)

This structure is foreign to Anderson. See applicants' figure 46 which is an example of this claimed structure. There is no corresponding figure or description in Anderson to this claimed subject matter as underlined directed to the abutting

adjacent sheets extending transversely the length direction. This claim is rejected as being anticipated by Anderson. Perhaps the Examiner has confused this claim with claim 1 because a pin is included because the Office Action comments are only directed to a pin. However, the offset relationship of the pin is not claimed in claim 80 as in claim 1. Thus, there is no suggestion much less anticipation in this reference of this claimed subject matter. This claim is grouped together with claim 1 for purposes of the Office Action rejection. However, the subject matters of claims 1 and 80 are completely different and are directed to different structures. It is error to reject this claim based on the subject matter of claim 1. Anderson neither suggests nor anticipates this claim. This claim is believed allowable and this rejection should be withdrawn as being improper.

Amended Claim 114

This claim calls for:

A spinal implant comprising:
first and second cortical bone planks each having fibers oriented in a direction parallel to a vertebral load direction and normal to an insertion direction into the disc space between adjacent vertebra;
each plank having a non-demineralized interior and demineralized surfaces including a load bearing surface for abutting an adjacent vertebra; and
means for securing the planks to each other with the demineralized surfaces coextensive for bonding the surfaces together (underlining added)

This claim calls for only the surface of the planks to be demineralized. See

the specification page 25, paragraph 00136 stating: "Preferably the mating surfaces are partially demineralized to assist in bonding these surfaces together." Anderson does not disclose or suggest such partial demineralization of the surfaces to assist in bonding. This reference does not go so far. The reference at col. 12, lines 6-16 and col. 19, lines 15-37 refer to demineralizing bone, but is silent as to surface demineralization. This section specifically discloses demineralizing a cancellous bone disposed between two cortical bone planks not demineralized. This is not what is claimed. The demineralization is not disclosed as partial, much less for use at the surfaces of cortical bone for bonding as claimed. The amendment to claim 114 with respect to the bonding aspect does not raise a new issue as claim 127 calls for more specific structure for bonding bone using demineralized surfaces. Amended claim 114 is believed allowable.

Claim 127

This claim calls for:

A spinal implant comprising:

first and second planks of cortical bone each plank having opposing broad surfaces, the bone having fibers running generally in a direction parallel to the broad surfaces of each plank;

a broad surface of each plank being surface demineralized and abutting, the demineralized surfaces having an acid applied thereto to form crystals on the surface of each plank; and

forcing the abutting wet surfaces together to join the planks by interlocking the formed crystals of each bone;

the planks each having at least one bore that is surface demineralized, the bore having a longitudinal axis that is normal to the fiber direction; and
a cortical bone pin in the plank bores for securing the planks together.(underlining added)

This structure is not disclosed, suggested or otherwise made obvious by Anderson. The Office Action states that claim 127 is obvious in view of Anderson and points to column 19, lines 22-29; column 28, lines 13-14; and column 29, line 21. Column 19 refers to demineralization, column 28 refers to chemical connectors and known methods of biochemical surface modification, and column 29 refers to modifying the surface of the mechanical connector.

Col. 12 refers to demineralization of bone but not to surface demineralization. Col. 19, lines 22-23, refers to the "plank" as being demineralized, not just its surface, as claimed. Col. 28 refers to chemical connectors which include biocompatible adhesives. It states such connectors include any known methods of biochemical surface modification. Such methods are well known. Col. 29, line 21 etc. refers to modifications for protein absorption and to improve lubricity. Col. 29, lines 21 etc. also states the surface of the mechanical connector can be modified by methods well known to those of ordinary skill and include modification to influence cell adhesion and growth provided by oxydized polystyrene surface, ammonia plasma-treated surface and

plasma-deposited acetone or methanol film among others.

None of the above suggest claim 127 surface demineralization and then forming crystals on the demineralized surface of each plank, and interlocking the formed crystals of each bone. Anderson does not disclose forming crystals and interlocking the formed crystals on a demineralized surface of each bone. Neither of these elements of the claim are taught or suggested by Anderson, nor is any motivation found in Anderson to arrive at the claimed invention. No convincing line of reasoning is given as to why Anderson suggests the specifics of what is claimed. Anderson is merely an invitation to experiment which is proscribed, *In re Antonie* (See the MPEP 2144.05, pg. 2100-138, citing and discussing this case). This case states there must be recognition in the prior art of the result effective variable that is being claimed. Anderson merely refers to that which is well known in the art without any mention of the specific surface demineralization. Surface demineralization changes and weakens the surface without changing the strength and characteristics of the underlying bone core which is not surface demineralized. Anderson and no other reference is cited that specifically describes or suggests only surface demineralizing a bone, applying an acid to the surface and forcing the wet surfaces together to bond the bones by interlocking the crystals as claimed. Anderson only refers to what is well known without the specifics of what is claimed being disclosed.

The Office Action assumes what is claimed is well known based on Anderson's description, but this assumption is faulty. There is no specific teaching of surface demineralization first and then apply an acid and pressing the wet surfaces together to form a mechanical bond as claimed. Anderson's general statements as to forming mechanical connectors does not disclosed or suggest the specific mechanisms as claimed. Generally alluding to mechanical connectors is insufficient. Claim 127 is not claiming a mechanical connector per se literally. It is more specific. These specifics are missing in Anderson. No where does Anderson refer to surface demineralization. It is error to ignore express limitations. See MPEP 2143.03 states that all limitations must be considered. the proposed modification can not make the prior art unsatisfactory for its intended purpose. The demineralization of cancellous bone disclosed by Anderson is to place this bone adjacent to and between non-demineralized cortical bone, col. 19, lines 15-17 and refers to demineralizing the entire plank, lines 15-36. This teaches away from demineralizing the surface only. Teaching away is the antithesis of obviousness. The fact that the claimed invention is within the capabilities of one of ordinary skill is insufficient to support an obvious conclusion. MPEP 2143.01, pg. 2100-126. Here it is stated that the court reversed an obvious rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a

skilled artisan that would have motivated the skilled artisan to make the claimed invention. The level of skill can not be relied upon to provide a suggestion to do what is claimed. Anderson does not suggest or disclose the claim 127 subject matter of surface demineralization and bonding such surfaces, but merely alludes to general demineralization concepts. This is not enough. Claim 127 is believed allowable.

The dependent claims depend from and include all of the structure of the independent claims from which they depend and are believed allowable at least for the same reasons as well as for the additional structures claimed therein.

For the reasons given, claims 1-10, 12-14, 18-20, 22, 23, 25-29, 33, 60-63, 72, 73, 80, 114-116, and 127 are believed to be in condition for allowance, and such favorable action is hereby solicited.

No fee is believed due for this paper. The Commissioner is authorized to charge any fees due for this paper or credit any overpayments to Deposit Account No. 03-0678.

FIRST CLASS CERTIFICATE

I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

 William Squire

 5/18/04
Date

Respectfully submitted,
Lawrence A. Shimp et al.

By: 
William Squire, Reg. No. 25,378
Attorney for Applicants

Phone: 973-994-1700
Fax: 973-994-1744

204862v2